

**Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100**

REFUSED

February 15, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 34

Curt Noyes, RT
Executive Vice President
Dakota Clinic, Ltd.
1702 S. University Drive
Fargo, North Dakota 58108

Dear Mr. Noves:

Between December 28, 2000 and January 30, 2001, representatives of the States of North Dakota and Minnesota, acting on behalf of the Food and Drug Administration (FDA) inspected your mobile mammography facility (FDA certification #214486). The equipment portion of the inspection was completed on December 28, 2000. Further inspectional data was collected by State inspectors during the period from December 28, 2000, - January 30, 2001, at the remote sites visited by this mobile unit. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. Based on the documentation your site presented at the time of the inspection, the following Level 1 and Level 2 findings were documented at your facility:

Level 1 Non-Compliance:

1. Film processor QC records were missing one out of two days of operation in the month of August 2000 (50%). (Processor = Winn-Dixie located at Main X-Ray; Remote site – Menagha, MN.)


The State of Minnesota inspector also reported that on days that the data did exist, it had reportedly been generated either concurrent with:

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mammography exams or after mammography exams had been completed. It is required that this test be performed prior to processing mammography films.


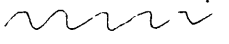

Repeat Level 2 Non-Compliance:

2. Based on documentation supplied during (or subsequent) to the inspection, Interpreting physician  did not meet the continuing education requirement of having completed a minimum of 15 CME in mammography in a 36-month period. Documentation indicated only 5.2 hours.

Level 2 Non-Compliances:

3. Based on documentation supplied during (or subsequent to the inspection), Interpreting physician  did not meet the continuing experience requirement of having interpreted 960 mammography exams in a 24-month period. Documentation indicated 0 exams.

This item was originally listed in the Post Inspection Report under the heading "List of Claimed Items." No data was supplied.

4. On two days mammograms were processed at the Menagha, MN. remote site when the film processor was out of limits. (Processor = 
 located at main x-ray.)
5. The Phantom QC test for your mobile  mammography system (ACR designation = Unit #1) is not adequate because the operating level for the background density was <1.20 OD.

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility following the close of the inspection.

Individuals failing to meet either the "Initial" and/or "Continuing" MQSA requirements must immediately cease performing mammography independently. Conditions for "Direct Supervision" of unqualified personnel are specified in regulation and formal FDA policy. Policy references may be found at the Internet address below. For physicians, "Continuing" requirements include both the number of mammography CME/24 months and the number of mammography interpretations/36 months. Requirements for re-qualification are listed in the Final Regulation that became effective on April 28, 1999.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a

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serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within 15 working days from the date you received this letter:

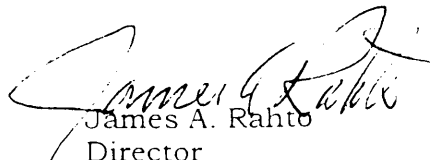
- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures if the findings relate to quality control or other records.

Please submit your response to Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 No. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov/cdrh/mammography/index.html>.

If you have specific questions about mammography facility requirements or about the content of this letter please feel free to phone Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,


James A. Rahto
Director
Minneapolis District